January 18, 2024

Sarah Spence
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Spence,

The OAS Executive Board (Board) appreciates the opportunity to comment on the Draft ABK Biomedical, Inc. Eye90 Microspheres® Manual Brachytherapy Licensing Guidance (RCPD-23-005). After reviewing the draft guidance, and after receiving comments from our Agreement State partners, the Board has the following comments on the draft guidance:

1. When compared with the current Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, it is not clear why Eye90 microspheres® warrants a unique licensing guidance. There are notable differences between TheraSphere® (unit dose) and SIR-Spheres® (bulk dose) including differences in microsphere particle size, yet those differences do not warrant separate licensing guidance. The vast majority of the content for the draft Eye90 microspheres® is identical to the current guidance (sections 6.2.3 and 7.5 appear to be the only major differences). Revising the current guidance to include Eye90 microspheres® would provide a singular licensing guidance for similar therapies.

    a. If there are unique differences to Eye90 microspheres®, such as a difference in microcatheter delivery systems; unit dose vial design that makes it vulnerable to dose delivery issues; differences in shunting that differ from other types of microspheres; and differences in particle size that potentially result in a greater probability of stasis occurring; then those differences should be included in the licensing guidance to assist in the consistent regulation of this therapy.

2. It appears that only Type A broad scope licensees that perform their own internal safety evaluation would be able to use Eye90 microspheres® until the Sealed Source and Device (SSD) registration certificate is issued. Developing guidance for Eye90 microspheres® to prepare for the eventual use is appropriate; however, issuing guidance prior to issuance of the SSD registration certification may be premature.

    a. If a guidance document is issued prior to the issuance of the SSD registration certification, the Agreement States will need to be notified once the SSD registration certification is complete to ensure consistent regulation across the National Materials Program.

3. For the Training and Experience section:

    a. In footnote 3, it is not clear why the footnote includes the language "…the NRC-approved ABR and AOBR certificates contain the words "AU Eligible" above the ABR or AORB seal" since the ABR discontinued the "AU Eligible" distinction. As noted in the same footnote, certificated issued without "AU Eligible" are adequate to meet the training and experience guidelines. This footnote should be revised for clarity.
    b. It appears that the current microsphere guidance document was used as a template for the training and experience section. However, this caused a number of incorrect footnote references throughout Sections 5.1 and 5.3 and all the footnotes should be reviewed to ensure they are referencing the correct item.

4. For Section 6.7, Patient Release, the Eye90 microsphere® guidance and Regulatory Guide 8.39 should provide consistent guidance concerning patient release criteria.

Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,

Keisha Cornelius, Chair
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